IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Curt R. Freed *et al.*
Serial No.: 10/699,302 Group No.: 1647
Filed: 10/30/2003 Examiner: Gamett, D.
Entitled: **Dopamine Neurons From Human Embryonic Stem Cells**

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: September 22, 2006 By: Christopher J. Collins

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent Number 6,277,820 to Rosenthal *et al.*;
- Bottenstein, in Cell Culture in the Neurosciences, Bottenstein and Harvey (eds.), Plenum Press: NY, p. 3, 1985[1];
- Clarkson *et al.*,"IGF-I and bFGF improve dopamine neuron survival and behavioral outcome in parkinsonian rats receiving cultured human fetal tissue strands," *Exp Neurol*, 168:183-191, 2001;
- Cotzias *et al.*, "Aromatic amino acids and modification of parkinsonism," *N. Engl. J. Med.*, 276:374-379, 1967;
- Dale and Federman (eds.), WebMD Scientific American Medicine, NY: WebMD Corporation, Chapter 11, Section 15, pp.1-21, 2001;

[1]We have been unable to obtain this reference, but if the examiner request a copy we will seek to obtain it.

- Echelard *et al.*,"Sonic hedgehog, a member of a family of putative signaling molecules, is implicated in the regulation of CNS polarity," *Cell* 75:1417-1430, 1993;
- Fahn *et al.*, in Recent Developments in Parkinson's Disease, Fahn *et al.* (eds.) Plurham Park, NJ: Macmillian Healthcare Information, 2:153-163, 1987[2];
- Freed *et al.*,"Transplantation of human fetal dopamine cells for parkinson's disease," *Arch Neurol*, 47:505-512, 1990;
- Freed *et al.*,"Transplantation of embryonic dopamine neurons for severe parkinson's disease," *N. Engl. J. Med.*, 344:710-719, 2001;
- He *et al.*,"A simplified system for generating recombinant adenoviruses," *Proc. Natl. Acad. Sci. USA*, 95:2509-2514, 1998;
- Hynes and Rosenthal, "Specification of dopaminergic and serotonergic neurons in the vertebrate CNS," *Curr Opin Neurobiol*, 9:26-36, 1999;
- Hynes *et al.*,"Induction of midbrain dopaminergic neutons by sonic hedgehog," *Neuron*, 15:35-44, 1995;
- Itoh *et al.*, "Reproducible establishment of hemopoietic supportive stromal cell lines from murine bone marrow," *Exp. Hematol.*, 17:145-153, 1989;
- Kawasaki *et al.*, "Induction of midbrain dopaminergic neurons from cell by stromal cell-derived inducing activity," *Neuron*, 28:31-40, 2000;
- Kodama *et al.*, "A new preadipose cell line derived from newborn mouse calvaria can promote the proliferation of pluripotent hemopoietic stem cells in vitro," *J Cell Physiol*, 112:89-95, 1982;
- Kordower *et al.*, "Neuropathological evidence of graft survival and striatal reinnervation after the transplantation of fetal mesencephalic tissue in a patient with parkinson's disease," *N. Engl. J. Med.*, 332:1118-1124, 1995;
- Krauss *et al.*,"A functionally conserved homolog of the drosophila segment polarity gene *hh* is expressed in tissues with polarity activity in zebrafish embryos," *Cell* 75:1431-1444, 1993;
- Lang and Lozano, "Parkinson's disease - first of two parts," *N. Engl. J. Med.*, 339:1044-1053, 1998;
- Lang and Lozano, "Parkinson's disease - second of two parts," *N. Engl. J. Med.*, 339:1130-1143, 1998;
- Langston *et al.*, *"Core assessment program for intracerebral transplantations (CAPIT),"* *Mov Disord*, 7:2-13, 1992;

[2]We have been unable to obtain this reference, but if the examiner request a copy we will seek to obtain it.

- Lin *et al.*, "GDNF: a glial cell line - derived neurotrophic factor for midbrain dopaminergic neurons," *Science*, 260:1130-1132, 1993;
- Lindvall *et al.*, "Grafts of fetal dopamine neurons survive and improve motor function in parkinson's disease," *Science*, 247:574-577, 1990;
- Marigo *et al.*,"Cloning, expression, and chromosomal location of *shh* and *ihh*: two human homologues of the drosophila segment polarity gene hedgehog," *Genomics* 28:44-51, 1995;
- Richards *et al.*, "Unilateral dopamine depletion causes bilateral deficits in conditioned rotation in rats," *Pharmacol. Biochem. Behav.*, 36:217-223, 1990;
- Riddle *et al.*,"Sonic hedgehog mediates the polarizing activity of the ZPA,"*Cell* 75:1401-1416, 1993;
- Schwab and England, in Third Symposium on Parkinson's Disease, Gillingham and Donaldon (eds.) Edinburgh, Scotland: Livingstone, "Projection technique for evaluating surgery in parkinson's disease," pp. 152-157, 1969;
- Simeone *et al.*,"A vertebrate gene related to orthodenticle contains a homeodomain of the bicoid class and demarcates anterior neuroectoderm in the gastrulating mouse embryo," *EMBO J.*, 12:2735-2747, 1993;
- Simeone,"Otx1 and Otx2 in the development and evolution of the mammalian brain," *EMBO J.*, 17:6790-6798, 1998;
- Trott *et al.*, "Cognition following bilateral implants of embryonic dopamine neurons in PD: a double blind study," *Neurology*, 60:1938-1943, 2003;
- Wang *et al.*, "Induction of dopaminergic neuron phenotype in the midbrain by sonic hedgehog protein," *Nat Med.*, 1:1184-1188, 1995; and
- Ye *et al.*, "FGF and shh signals control dopaminergic and serotonergic cell fate in the anterior neural plate," *Cell*, 93:755-766, 1998;

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- Lee *et al.*, "Efficient generation of midbrain and hindbrain neurons from mouse embryonic stem cells," *Nature Biotech* 18:675-679, 2000.
- U.S. Patent Number 5,411,883 to Boss *et al.*;.
- U.S. Patent Number 5,750,376 to Weiss *et al.*.
- U.S. Patent Number 5,753,506 to Johe.
- U.S. Patent Number 5,766,948 to Gage *et al.*.
- U.S. Patent Number 5,968,829 to Carpentar.
- U.S. Patent Number 6,013,521 Gage *et al.*.
- U.S. Patent Number 6,020,197 Gage *et al.*.

- U.S. Patent Number 6,045,807 to Gage *et al.*.
- U.S. Patent Number 6,103,530 to Carpentar.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: September 22, 2006

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FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: UTC-07994	Serial No.:10/699,302
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)		Applicant: Freed *et al.*	
(37 CFR § 1.98(b))		Filing Date: 10/30/2003	Group Art Unit: 1647

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	5,411,883	5/02/95	Boss *et al.*	435	240.2	8/12/92
	2	5,750,376	5/12/98	Weiss *et al.*	435	69.52	6/17/95
	3	5,753,506	5/19/98	Johe	435	377	9/25/96
	4	5,766,948	6/16/98	Gage *et al.*	435	368	11/03/93
	5	5,968,829	10/19/99	Carpentar	435	467	9/05/97
	6	6,013,521	1/11/00	Gage *et al.*	435	368	4/24/98
	7	6,020,197	2/01/00	Gage *et al.*	435	368	4/24/98
	8	6,045,807	4/04/00	Gage *et al.*	435	368	6/10/98
	9	6,103,530	8/15/00	Carpentar	435	405	10/23/98
	10	6,277,820	8/21/01	Rosenthal *et al.*	514	12	4/19/98

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

	11	Clarkson *et al.*, "IGF-I and bFGF improve dopamine neuron survival and behavioral outcome in parkinsonian rats receiving cultured human fetal tissue strands," *Exp Neurol*, 168:183-191, 2001
	12	Cotzias *et al.*, "Aromatic amino acids and modification of parkinsonism," *N. Engl. J. Med.*, 276:374-379, 1967
	13	Dale and Federman (eds.), WebMD Scientific American Medicine, NY: WebMD Corporation, Chapter 11, Section 15, pp.1-21, 2001
	14	Echelard *et al.*, "Sonic hedgehog, a member of a family of putative signaling molecules, is implicated in the regulation of CNS polarity," *Cell* 75:1417-1430, 1993
	15	Freed *et al.*, "Transplantation of human fetal dopamine cells for parkinson's disease," *Arch Neurol*, 47:505-512, 1990
	16	Freed *et al.*, "Transplantation of embryonic dopamine neurons for severe parkinson's disease," *N. Engl. J. Med.*, 344:710-719, 2001
	17	He *et al.*, "A simplified system for generating recombinant adenoviruses," *Proc. Natl. Acad. Sci. USA*, 95:2509-2514, 1998
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	20	Kawasaki *et al.*, "Induction of midbrain dopaminergic neurons from cell by stromal cell-derived inducing activity," *Neuron*, 28:31-40, 2000
	21	Kodama *et al.*, "A new preadipose cell line derived from newborn mouse calvaria can promote the proliferation of pluripotent hemopoietic stem cells in vitro," *J Cell Physiol*, 112:89-95, 1982
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	23	Krauss *et al.*, "A functionally conserved homolog of the drosophila segment polarity gene *hh* is expressed in tissues with polarity activity in zebrafish embryos," *Cell* 75:1431-1444, 1993
	24	Lang and Lozano, "Parkinson's disease - first of two parts," *N. Engl. J. Med.*, 339:1044-1053, 1998
	25	Lang and Lozano, "Parkinson's disease - second of two parts," *N. Engl. J. Med.*, 339:1130-1143, 1998

Examiner:	Date Considered:

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: UTC-07994	Serial No.: 10/699,302
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)	Applicant: Freed *et al.*	
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	26	Langston *et al., "Core assessment program for intracerebral transplantations (CAPIT)," Mov Disord*, 7:2-13, 1992
	27	Lee *et al.*, "Efficient generation of midbrain and hindbrain neurons from mouse embryonic stem cells," *Nature Biotech* 18:675-679, 2000.
	28	Lin *et al.*, "GDNF: a glial cell line - derived neurotrophic factor for midbrain dopaminergic neurons," *Science*, 260:1130-1132, 1993
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	31	Richards *et al.*, "Unilateral dopamine depletion causes bilateral deficits in conditioned rotation in rats," *Pharmacol. Biochem. Behav.*, 36:217-223, 1990
	32	Riddle *et al.*, "Sonic hedgehog mediates the polarizing activity of the ZPA," *Cell* 75:1401-1416, 1993
	33	Schwab and England, in Third Symposium on Parkinson's Disease, Gillingham and Donaldon (eds.) Edinburgh, Scotland: Livingstone, "Projection technique for evaluating surgery in parkinson's disease," pp. 152-157, 1969
	34	Simeone *et al.*, "A vertebrate gene related to orthodenticle contains a homeodomain of the bicoid class and demarcates anterior neuroectoderm in the gastrulating mouse embryo," *EMBO J.*, 12:2735-2747, 1993
	35	Simeone, "Otx1 and Otx2 in the development and evolution of the mammalian brain," *EMBO J.*, 17:6790-6798, 1998
	36	Trott *et al.*, "Cognition following bilateral implants of embryonic dopamine neurons in PD: a double blind study," *Neurology*, 60:1938-1943, 2003
	37	Wang *et al.*, "Induction of dopaminergic neuron phenotype in the midbrain by sonic hedgehog protein," *Nat Med.*, 1:1184-1188, 1995
	38	Ye *et al.*, "FGF and shh signals control dopaminergic and serotonergic cell fate in the anterior neural plate," *Cell*, 93:755-766, 1998
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